

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1027 Biomedical Research
SPONSOR(S): Hasner, Coley and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1826

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) <u>Health Care General Committee</u>	<u>9 Y, 0 N</u>	<u>Ciccone</u>	<u>Brown-Barrios</u>
2) <u>Health Care Appropriations Committee</u>	<u></u>	<u></u>	<u></u>
3) <u>Health & Families Council</u>	<u></u>	<u></u>	<u></u>
4) <u></u>	<u></u>	<u></u>	<u></u>
5) <u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

This bill provides legislative intent to provide funding to support grants for biomedical research in Florida with particular emphasis on cancer research and Alzheimer's disease research. The bill amends several statutes that govern state funding for biomedical research.

The bill requires that the Florida Center for Universal Research to Eradicate Disease (CURED) provide grants for cancer research to further the search for cures of cancer and authorizes the center to give preference to grant proposals that foster collaborations between institutions, researchers, and community practitioners. The bill requires that state-funded biomedical research grants be awarded on a competitive basis subject to a peer review process.

The bill establishes the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program in the Department of Health and expands the purpose of the CURED center to include providing grants through the newly established research program. The bill revises the composition of the CURED center's advisory council and establishes 4-year terms for advisory board members and requirements for the election of a chair and for periodic board meetings.

The bill discontinues the automatic annual distribution of alcoholic beverage tax collections from the State Treasure for the Center for Universal Research to Eradicate Disease, the James and Esther King Biomedical Research Program, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and provides for an annual appropriation for these programs. The bill requires the Department of Health to submit an annual report on the William G. "Bill" Bankhead, Jr. and David Coley Cancer Research Program. Further the bill requires the annual operating budget for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute be submitted to the Governor and Cabinet, Senate President, House Speaker and State Board of Education chair and requires additional information regarding the center's expenditure of funds and research.

The bill includes appropriations as follows:

- \$6 million to the James and Esther King Biomedical Research Program,
- \$9 million to the CURED center; and
- \$15 million to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute,

The bill provides for an effective date of July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited Government - Adds a new grant program and expands the administrative and oversight responsibility of the Department of Health.

Empower families - Florida families should benefit from greater access to information and health care services derived from cancer and Alzheimer's disease clinical trials and resultant new therapies.

B. EFFECT OF PROPOSED CHANGES:

The Florida Center for Universal Research to Eradicate Disease is located within the University of South Florida. The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for cancer and other diseases including Alzheimer's disease. The bill creates the William G. "Bill" Bankhead and David Coley Cancer Research Program within the Department of Health thereby expanding the purpose of the CURED center to provide grants through this newly established Bankhead-Coley Cancer Research Program. The bill replaces the automatic annual appropriation with a \$9 million non-recurring appropriation.

The bill revises the composition of the center's advisory council to provide for an 18-member board instead of the current 54-member board by requiring one member from the Florida Research Consortium rather than all 37 members of the consortium board of directors.

Florida Cancer Council is located within the Department of Health. The purpose of the Council is to establish the state as a center of excellence for cancer research by expanding cancer research capacity, improving research and treatment through greater clinical trial participation, and reducing the impact of cancer in disparate groups. The council must work in concert with the Florida Center for Universal Research to Eradicate Disease (CURED) to ensure that the goals of the center are advanced. The bill provides that the council will identify ways to attract new research talent and national grant-producing researchers to cancer research facilities "in this state" rather than "Florida-based" facilities. The effect of this change is to expand the types of facilities that may be awarded grants. Grant funding decisions would be based on a peer-review system according to specific criteria.

The Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute is located within the University of South Florida. The purpose of the Center is to encourage research, education, treatment, prevention and the early detection of Alzheimer's disease. The bill revises the information contained within the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute's annual report to include a description of the expenditure of all funds, information concerning research conducted or funded by the center, and the expected or actual result of such research. Further, the center's chief executive officer is required to submit an annual operating budget to the Governor, Cabinet, Senate President, House Speaker and State Board of Education chair. The bill replaces the automatic \$15 million distribution from alcoholic beverage tax collection with a \$15 million non-recurring appropriation.

The bill reduces the Governor's appointments to the Biomedical Research Advisory Council from six to four and requires one appointment by the Senate President and one by the House Speaker. The bill replaces the automatic \$6 million distribution from alcoholic beverage tax collection with a \$6 million non-recurring appropriation.

Background:

Cancer Research:

The emphasis that Florida places on cancer research is evidenced in the high-profile cancer related programs and funding strategies that have been established over the years. In addition, Florida recognizes the importance of a coordinated and collaborative approach to biomedical research. The scientific, humanitarian and economic value that is derived from a coordinated state, federal, and academic and private effort can not be overstated. Ultimately, biomedical research contributes to a healthier population and biomedical discoveries and the resultant products or treatments contribute to the economy of the area in which they are produced. For both health and economic reasons, governments are interested in furthering the work of biomedical researchers and in helping researchers collaborate and share resources.

Efforts in Florida relating to the coordination and development of medical research and disease prevention include:

The James and Ester King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund ¹ funded as a result of its settlements with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Ester King Biomedical Research Program funded from earnings of the endowment fund and provided that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of scientific merit, as determined by an open, objective peer-review process.

The Florida Center for Universal Research to Eradicate Disease

Section 381.855, F.S., creates the Florida Center for Universal Research to Eradicate Disease within the Department of Health. The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy and Parkinson's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees are required to cover, or obtain sponsorship for, the costs of their attendance.

An advisory council, established within the center, must meet at least annually. The council consists of the members of the board of directors of the Florida Research Consortium and at least one representative from each of the following:

- The Emerging Technology Commission;
- Enterprise Florida, Inc;
- BioFlorida;
- The Biomedical Research Advisory Council;
- The Florida Medical Foundation;
- Pharmaceutical Research and Manufacturers of America;

¹ Section 215.5601, F.S., ch. 99-167, Laws of Florida

- The Florida Tri-Agency Coalition on Smoking and Health;
 - The Florida Cancer Research Council;
 - The American Cancer Society, Florida Division, Inc;
 - The American Heart Association;
 - The American Lung Association of Florida;
 - The American Diabetes Association, South Coastal Region;
 - The Alzheimer's Association;
 - The Epilepsy Foundation;
 - The National Parkinson's Foundation;
 - The Florida Public Health Foundation, Inc; and
 - Scripps Florida, or the entity formed by the Scripps Research Institute in Florida.
- Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

The Florida Cancer Council

In 2004, the Legislature created the Florida Cancer Council within the Department of Health for the purpose of making Florida a center of excellence for cancer research. ² Section 381.921, F.S., provides the overall mission of the Florida Cancer Council and stipulates that the council must work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced, and must work toward dramatically improve cancer research and treatment in Florida through a number of specific efforts including expanding cancer research capacity in Florida, improving research and treatment through greater participation in clinical trials networks, and reducing the impact of cancer on disparate groups of persons.

The Florida Cancer Council membership is representative of Florida cancer centers, hospitals, and patient groups. The council is authorized to create not-for-profit corporate subsidiaries to fulfill its mission and those subsidiaries could receive, hold, invest and administer property and any monies acquired from private, local, state and federal sources and technical and professional income from the mission-related activities of the council.

The council membership is as follows:

- The Chairman of the Florida Dialogue on Cancer, who serves as the council chairman;
- The Secretary of the Department of Health, or his or her designee;
- The Chief Executive Officer of the H. Lee Moffitt Cancer Center, or his or her designee;
- The President of the University of Florida Shands Cancer Center, or his or her designee;
- The Chief Executive Officer of the University of Miami Sylvester Comprehensive Cancer Center, or his or her designee;
- The Chief Executive Officer of the Mayo Clinic, Jacksonville, or his or her designee;
- The Chief Executive Officer of the American Cancer Society, Florida Division, or his or her designee;
- The President of the American Cancer Society, Florida Division Board of Directors, or his or her designee;
- The President of the Florida Society of Clinical Oncology, or his or her designee;
- The President of the American College of Surgeons, Florida Chapter, or his or her designee;
- The Chief Executive Officer of Enterprise Florida, Inc., or his or her designee;
- Five representatives from cancer programs approved by the American College of Surgeons. Three of whom shall be appointed by the Governor, one by the Speaker of the House of Representatives and one by the President of the Senate;
- One member of the House of Representatives, to be appointed by the Speaker of the House of Representatives; and
- One member of the Senate, to be appointed by the President of the Senate.

² Section 381.92, Florida Statutes, s.10, ch. 2004-2 Laws of Florida

Appointments made by the Speaker of the House of Representatives and the President of the Senate are two-year terms concurrent with the terms of the presiding officers who make the appointments. Appointments made by the Governor are two-year terms, and the Governor may reappoint directors. Members of the council or any subsidiaries serve without compensation and each organization represented covers the expenses of its representatives.

The council issues an annual report to the Center for Universal Research to Eradicate Disease, the Governor, the Speaker of the House of Representatives, and the President of the Senate by December 15th of each year. The report contains policy and funding recommendations regarding cancer research capacity in Florida and related issues.

The Florida Dialogue on Cancer

The Florida Dialogue on Cancer is a collaboration of Florida leaders of hospitals, research centers, universities, professional medical groups, community-based organizations, and private business groups, and government officials, FDOC is an initiative designed to expand the state's capacity to reduce the incidence and mortality rates of cancer. The goals of FDOC are to:

- Create a coalition that speaks with one voice on major statewide cancer issues for Florida;
- Enhance and promote Florida's capacity to conduct cancer research, professional education, clinical trials and treatment programs; and
- Identify and promote the replication of best practices in providing access to cancer prevention, education, and screening, diagnosis, and treatment programs for all Floridians to reduce the disparities that exist.

The Florida Division of the American Cancer Society sponsors FDOC, which is based on the work of the National Dialogue on Cancer.

Alzheimer's Disease:

Alzheimer's disease is a progressive, irreversible brain disorder with no known cause or cure. Symptoms of the disease include memory loss, confusion, impaired judgment, personality changes, disorientation, and loss of language skills. Alzheimer's disease is the most common form of irreversible dementia—symptom escalation varies from person to person and includes confusion, personality and behavior changes and impaired judgment. Most people with Alzheimer's disease become unable to care for themselves.

There is no known cure for Alzheimer's disease; however certain medications can help relieve symptoms or slow the progression of the disease. Approximately 100,000 victims die and 360,900 new cases of Alzheimer's disease are diagnosed each year in the United States. According to the Alzheimer's Association, the number of Americans with the disease has doubled since 1980 and current estimates reflect 4.5 million Americans have Alzheimer's disease. By 2050, it is estimated that 14 million Americans will have this disease. There are currently 396,000 people with Alzheimer's disease in Florida.

Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute:

Section 1004.43, F.S., establishes the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida. The institute is governed by a not-for-profit corporation in accordance with an agreement with the State Board of Education. The corporation is managed by a board of directors consisting of the President of the University of South Florida and the chair of the State Board of Education, or his or her designee, five representatives of the state university system, and between 9-14 additional directors who are not medical doctors or state employees. The institute is administered by a chief executive officer, who serves at the pleasure of the board of directors.

The mission of the Byrd Alzheimer's Research Center is to collaborate with researchers throughout the State of Florida and the wider global research community to develop treatment to cure and prevent this disease.

The Byrd Alzheimer's Research Center will conduct state of the art research in addition to serving as the site for coordinating and facilitating the state's various efforts to diagnose, treat and prevent the disease. Funding for the institute is generated through state and federal grants and other fundraising efforts.

C. SECTION DIRECTORY:

Section 1. Provides legislative intent.

Section 2. Amends s. 215.5602, F.S., relating to the membership of the Biomedical Research Advisory Council and to create a new subsection (11) authorizing an annual appropriation to the James and Esther King Biomedical Research Program.

Section 3. Provides language regarding the expiration of certain appointments to the Biomedical Research Advisory Council.

Section 4. Amends ss. 381.855 (3) (5), F.S., relating to Center for Universal Research to Eradicate Disease (CURED). Provides new language regarding the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and creates new subsections (6) (7) and (8), F.S., to revise advisory council membership, term and grant peer review process.

Section 5. Provides language regarding the expiration of certain appointments to the advisory council for the Center for Universal Research to Eradicate Disease (CURED).

Section 6. Amends ss 381.921 (1), F.S., relating to the mission and duties of the Florida Cancer Council.

Section 7. Creates s. 381.922, F.S., to establish the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

Section 8. Amends s. 561.121 (1), F.S., and deletes language relating to certain automatic annual distributions of alcoholic beverage tax collections from the State Treasury.

Section 9. Amends s. 1004.445 (2) (6), F.S., relating to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and creates new subsections (8) and (12) relating to research funding and authorizes an annual appropriation to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 10. Provides language regarding the expiration of certain appointments to the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 11. Provides for a \$6 million non-recurring appropriation from the General Revenue Fund to be deposited into the Biomedical Research Trust Fund; provides for a \$9 million non-recurring appropriation from the General Revenue Fund to be deposited into the Florida Center for Universal Research to Eradicate Disease; provides for a \$15 million non-recurring appropriation from the General Revenue fund to be deposited into the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; provides for specific use of such funds.

Section 12. Provides for an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

The Department of Health estimates the following expenditures:

Estimated Expenditures	1 st Year	2 nd Year (Annualized/Recur)
Salaries:		
1.5 Senior Attorney @\$4,795	\$70,138	\$72,242
1 Administrative Secretary @\$27,397	35,068	36,120
1 Program Administrator @\$57,000	72,960	75,149
1 Administrative Assistant @\$32,000	32,000	32,960
(FTE computed w/28% fringe; 3% annual increase In 2 nd year		
Expenses:		
1 Std DOH professional pkg. w/maximum travel (1 FTE)	\$19,097	\$15,867
2 Std DOH profession package w/limited travel (1.5 FTE)	27,640	21,000
2 Std DOH support pkg. (2 FTE)	16,300	10,728
Sub-contracting of grant management And major grant cycle processes	610,000	350,000
Council Travel	30,000	30,000
General Office Expenses	10,250	10,250
Staff Development	5,250	5,250
Operating Capital Outlay		
3 Std DOH professional pkg. (2 FTE)	5,400	- 0 -
2 Std DOH support Pkg. (2 FTE)	4,200	- 0 -
Human Resources Services		
5 FTEs	1,965	1,965
Total Estimated Expenditures	\$940,268	\$661,531

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By referring to research facilities as those which are "in this state", non-state universities, not-for-profit entities, researchers, biotechnology and pharmaceutical companies and others will benefit from this bill by receiving grants from which they may develop patented or licensed intellectual property. Further, new research talent and national grant-producing researchers should be attracted to cancer research facilities in this state.

Florida citizens should benefit from greater access to information and health care services derived from cancer clinical trials and resultant new therapies.

D. FISCAL COMMENTS:

The bill discontinues the annual distribution of alcoholic beverage tax collections from the State Treasury for the Center for Universal Research to Eradicate Disease (CURED), the James and Esther King Biomedical Research Program, and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute and provides instead for an annual appropriation by the Legislature.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill has no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

2. Other:

This bill has no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

No additional rule making is required for the Department of Health to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES